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EXAMINER

THANGAVELU, KANDASAMY

ART UNIT PAPER NUMBER

2123

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

24

Office Action Summary

Application N .

09/980,163

Applicant(s)

MOUNTASSIR, M'HAMMED

Examiner

Kandasamy Thangavelu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

DETAILED ACTION

Introduction

1. Claims 25-52 of the application have been examined.

Information Disclosure Statement

2. Acknowledgment is made of the information disclosure statements filed on November 30, 2001 together with copies of the patents and papers. The patents and papers have been considered in reviewing the claims.

Drawings

3. The drawings submitted on November 30, 2001 are accepted.

Specification

4. The disclosure is objected to because of the following informalities:
Page 9, Line 7, "a goal function in term of property weighted deviations" is incorrect.
Page 10, Line 9, "matrix is built between the properties of this level and presented at an input of the parameters weighting module 14 shown in Fig. 2" is incorrect. Also Fig. 2 does not have parameters weighting module 14, but Fig 1 has property weighting module 14.

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Page 10, Lines 20-22, "For example, to one or more m ... may correspond one or more ... at a second (lower) level" is incorrect.

Page 15, Line 27, "with highest weight values of the factor." The applicant has not described the term factor in the specification.

Page 16, Line 10, "The optimal property values X_{0i} " is incorrect. Property values are indicated by Y_i while parameters are indicated by X_i .

Page 18, Table 1, Run 3 has same parameters as Run 2 and Run 8 has same parameters as Run 7. This does not agree with what is being claimed.

Page 18, Line 13, "could be responsible of the appearance" is incorrect.

Page 21, Line 8, "since $n = 3 < 8$, is not understood.

Appropriate corrections are required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 25, 26 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459), and further in view of **Lemelson (LE)** (U.S. Patent 5,871,805).

7.1 **MO** teaches Optimization of process/property/compositional parameters. Specifically, as per claim 25, **MO** teaches a method of producing a product according to a process essentially controlled by a set of n parameters X_i affecting a set of k properties Y_j characterizing the product (Col 1, Lines 8-11); the method comprising:

establishing property behavior mathematical relations giving an estimated property Y_{ej} for each the property Y_j in terms of the parameters X_i from given parameter data and associated property data (Col 1, Lines 42-49; Col 1, Lines 53-61).

MO does not expressly teach assigning values to a set of k property weights w_j representing relative importance of the properties Y_j for the characterization of the product. **MA** teaches assigning values to a set of k property weights w_j representing relative importance of the properties Y_j for the characterization of the product (Col 15, Lines 11-22), as weighting provides different importance to different properties (Col 16, Lines 26-27) and it adds robustness to handle mismatch between process and prediction mode (Col 15, Lines 52-54). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the

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method of **MO** with the method of **MA** that included assigning values to a set of k property weights w_j representing relative importance of the properties Y_j for the characterization of the product, as weighting would provide different importance to different properties and it would add robustness to handle mismatch between process and prediction mode.

MO teaches using the property to establish a goal function in terms of property deviations between the estimated properties Y_{ej} and corresponding specified goal values for the properties Y_j (Col 1, Line 67 to Col 2, Line 23). **MO** does not expressly teach using the property weights w_j to establish a goal function in terms of property weighted deviations between the estimated properties Y_{ej} and corresponding specified goal values for the properties Y_j . **MA** teaches using the property weights w_j to establish a goal function in terms of property weighted deviations between the estimated properties Y_{ej} and corresponding specified goal values for the properties Y_j (Col 14, Lines 4-6; Col 15, Lines 11-22), as weighting provides different importance to different properties in the objective or goal function (Col 16, Lines 26-27) and it adds robustness to handle mismatch between process and prediction mode (Col 15, Lines 52-54). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO** with the method of **MA** that included using the property weights w_j to establish a goal function in terms of property weighted deviations between the estimated properties Y_{ej} and corresponding specified goal values for the properties Y_j , as weighting would provide different importance to different properties in the objective or goal function and it would add robustness to handle mismatch between process and prediction mode.

MO teaches minimizing the goal function (Col 2, Lines 33-34). **MO** does not expressly teach minimizing the goal function to generate a set of n optimal parameter values for the

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parameters X_i . **LE** teaches minimizing the goal function to generate a set of n optimal parameter values for the parameters X_i (Col 10, Lines 2-15), as the values so selected for the parameters will reflect the best outcome for the properties (Col 10, Lines 12-14). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO** with the method of **LE** that included minimizing the goal function to generate a set of n optimal parameter values for the parameters X_i , as the values so selected for the parameters would reflect the best outcome for the properties.

MO does not expressly teach using the set of optimal parameter values in the process to produce the product. **LE** teaches using the set of optimal parameter values in the process to produce the product (Col 1, Lines 5-7; Col 4, Line 66 to Col 5, Line 2), as that will tailor the process to the process goals (Col 4, Lines 63-64). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO** with the method of **LE** that included using the set of optimal parameter values in the process to produce the product, as that would tailor the process to the process goals.

7.2 As per Claim 26, **MO**, **MA** and **LE** teach the method of claim 25. **MO** also teaches the product is a composition of matter, the set of optimal parameter values characterizing an optimal formulation for the composition (Col 1, Lines 8-11).

7.3 As per Claim 34, **MO**, **MA** and **LE** teach the method of claim 25. **MO** and **LE** do not expressly teach that the goal function is expressed as $G(X_1, \dots, X_n) = \sum_{i=1}^k w_j^2 (Y_{ej} - O_j)^2$ wherein O_j are the specified goal values for the properties Y_j . **MA** teaches that the goal function

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is expressed as $G(X_1, \dots, X_n) = \sum_{j=1}^k w_j^2 (Y_{ej} - O_j)^2$ wherein O_j are the specified goal values for the properties Y_j (Col 15, Lines 11-22), as weighting provides different importance to different properties (Col 16, Lines 26-27) and it adds robustness to handle mismatch between process and prediction mode (Col 15, Lines 52-54) and minimizing the square of errors gives importance to a few large errors over many small errors. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO** and **LE** with the method of **MA** that included assigning values to a set of k property weights w_j representing relative importance of the properties Y_j for the characterization of the product, as weighting would provide different importance to different properties and it would add robustness to handle mismatch between process and prediction mode and minimizing the square of errors would give importance to a few large errors over many small errors.

7.4 As per Claim 35, **MO**, **MA** and **LE** teach the method of claim 34. **MO** also teaches that the minimizing step is performed by successive iterations of $G(X_1, \dots, X_n) = \sum_{i=1}^k [f_i(X_1, \dots, X_n)]^2$ (Col 1, Line 58 to Col 2, Line 34).

7.5 As per Claim 36, **MO**, **MA** and **LE** teach the method of claim 35. **MO** also teaches that the goal function is minimized according to one or more specified ranges (a_i, b_i) wherein $a_i < X_i < b_i$ for one or more of the optimal parameter values (Col 2, Lines 17-23).

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8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459) and **Lemelson (LE)** (U.S. Patent 5,871,805), and further in view of **Huse et al. (HU)** (U.S. Patent 5,862,514).

8.1 As per Claim 27, **MO**, **MA** and **LE** teach the method of claim 26. **MO**, **MA** and **LE** do not expressly teach that the product is a pharmaceutical product, the set of optimal parameter values characterizing an optimal formulation for the pharmaceutical product. **HU** teaches that the product is a pharmaceutical product, the set of optimal parameter values characterizing an optimal formulation for the pharmaceutical product (Col 2, Lines 41-54), as that enhances the efficiency with which the drugs are discovered and developed (Col 2, Lines 43-45). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA** and **LE** with the method of **HU** that included the product being a pharmaceutical product, the set of optimal parameter values characterizing an optimal formulation for the pharmaceutical product, as that would enhance the efficiency with which the drugs are discovered and developed.

9. Claim 28 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459) and **Lemelson (LE)** (U.S. Patent 5,871,805), and further in view of **Lobley et al. (LO)** (U.S. Patent 6,151,565).

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9.1 As per Claim 28, **MO**, **MA** and **LE** teach the method of claim 25. **MO**, **MA** and **LE** do not expressly teach that the values for the property weights w_j are obtained using an algorithm based on an analytic hierarchy process. **LO** teaches that the values for the property weights w_j are obtained using an algorithm based on an analytic hierarchy process (Col 1, Lines 47-56), as that determines the weighting of various factors using pair-wise comparison of the factors, each factor being compared to each other factor after the factors are arranged in a hierarchical order (Col 1, Lines 49-56). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA** and **LE** with the method of **LO** that included the values for the property weights w_j being obtained using an algorithm based on an analytic hierarchy process, as that would determine the weighting of various factors using pair-wise comparison of the factors,, each factor being compared to each other factor after the factors are arranged in a hierarchical order.

9.2 As per Claim 37, **MO**, **MA** and **LE** teach the method of claim 25. **MO** also teaches performing experimentally the process using the set of optimal parameters values to obtain corresponding experimental values for the properties Y_j (Col 2, Lines 17-23).

MO, **MA** and **LE** do not expressly teach ranking the set of optimal parameters values over predetermined alternative sets of parameters values for the X_i . **LO** teaches ranking the set of optimal parameters values over predetermined alternative sets of parameters values for the X_i (Col 1, Lines 47-56), as that allows comparison of each factor to each other factor after the factors are arranged in a hierarchical order and determination of the weighting of various factors using pair-wise comparison of the factors (Col 1, Lines 49-56). It would have been obvious to

one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA** and **LE** with the method of **LO** that included ranking the set of optimal parameters values over predetermined alternative sets of parameters values for the X_i , as that would allow comparison of each factor to each other factor after the factors were arranged in a hierarchical order and determination of the weighting of various factors using pair-wise comparison of the factors.

9.3 As per Claim 38, **MO**, **MA**, **LE** and **LO** teach the method of claim 37. **MO**, **MA** and **LE** do not expressly teach that the ranking step is performed using an algorithm based on an analytic hierarchy process. **LO** teaches that the ranking step is performed using an algorithm based on an analytic hierarchy process (Col 1, Lines 47-56), as that allows comparison of each factor to each other factor after the factors are arranged in a hierarchical order and determination of the weighting of various factors using pair-wise comparison of the factors (Col 1, Lines 49-56). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA** and **LE** with the method of **LO** that included the ranking step being performed using an algorithm based on an analytic hierarchy process, as that would allow comparison of each factor to each other factor after the factors were arranged in a hierarchical order and determination of the weighting of various factors using pair-wise comparison of the factors.

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9.4 As per Claim 39, **MO**, **MA**, **LE** and **LO** teach the method of claim 37. **MO** also teaches incorporating the set of optimal parameters values and the corresponding experimental values for the properties Y_j respectively into the given parameter and associated property data (Col 1, Lines 58-59).

MO, **MA** and **LO** do not expressly teach repeating the steps ii) to iv) to generate a new set of optimal parameters values for the parameters X_i . **LE** teaches repeating the steps ii) to iv) to generate a new set of optimal parameters values for the parameters X_i (Col 10, Lines 2-15), as the values so selected for the parameters will reflect the best outcome for the properties (Col 10, Lines 12-14). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA** and **LO** with the method of **LE** that included repeating the steps ii) to iv) to generate a new set of optimal parameters values for the parameters X_i , as the values so selected for the parameters would reflect the best outcome for the properties.

10. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459) and **Lemelson (LE)** (U.S. Patent 5,871,805), and further in view of **Lobley et al. (LO)** (U.S. Patent 6,151,565) and **Li (LI)** (U.S. Patent 4,368,509).

10.1 As per Claim 29, **MO**, **MA**, **LE** and **LO** teach the method of claim 28. **MO**, **MA**, **LE** and **LO** do not expressly teach that the given property data are obtained through a number l of experimental runs of the process using the given parameter data, each the run using a distinct set

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of values for the given parameter data. **LI** teaches that the given property data are obtained through a number l of experimental runs of the process using the given parameter data, each the run using a distinct set of values for the given parameter data (Col 3, Lines 38-43; Col 4, Lines 16-44; Col 8, Table 1), as that allows analyzing the data to determine the functional relationship between the variables and the properties (Col 3, Lines 43-46). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE** and **LO** with the method of **LI** that included the given property data being obtained through a number l of experimental runs of the process using the given parameter data, each the run using a distinct set of values for the given parameter data, as that would allow analyzing the data to determine the functional relationship between the variables and the properties.

11. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459), **Lemelson (LE)** (U.S. Patent 5,871,805), **Lobley et al. (LO)** (U.S. Patent 6,151,565) and **Li (LI)** (U.S. Patent 4,368,509), and further in view of **NIST (NI)** (Engineering Statistics Handbook).

11.1 As per Claim 30, **MO**, **MA**, **LE**, **LO** and **LI** teach the method of claim 29. **MO**, **MA**, **LE**, **LO** and **LI** do not expressly teach that the number of experimental runs of the process each uses a selected distinct set of values for the parameters X_i covering substantially all extreme values within a chosen range of values for each one of the parameters X_i . **NI** teaches that the number of experimental runs of the process each uses a selected distinct set of values for the parameters X_i covering substantially all extreme values within a chosen range of values for each

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one of the parameters X_i (Page 8, Para 2 and Page 9, Para 1), as that gives most of the information required (Page 8, Para 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE**, **LO** and **LI** with the method of **NI** that included that the number of experimental runs of the process each using a selected distinct set of values for the parameters X_i covering substantially all extreme values within a chosen range of values for each one of the parameters X_i , as that would give most of the information required.

MO, **MA**, **LE** and **LO** do not expressly teach that l is at least equal to $n + 1$ and is substantially less than a number used in the Fractional Factorial Matrix method. **NI** teaches that a fractional factorial design is one in which only an adequately chosen fraction of the combinations required for the complete factorial experiments is selected to be run (Page 11, Para 1) and a fraction such as $1/2$, $1/4$ etc. of the runs called for by full factorial is selected (Page 11, Para 3), as that would reduce the resource requirements for the runs (Page 11, Para 2). **LI** teaches that l is at least equal to $n + 1$ and is substantially less than a number used in the Fractional Factorial Matrix method (Col 4, Lines 16-44; Col 8, Table 1), as the savings in resources required is substantial (Col 5, Lines 2-3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE** and **LO** with the method of **LI** that included l at least equal to $n + 1$ and substantially less than a number used in the Fractional Factorial Matrix method, as the savings in resources required would be substantial.

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12. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459), **Lemelson (LE)** (U.S. Patent 5,871,805) and **Huse et al. (HU)** (U.S. Patent 5,862,514), and further in view of **Lobley et al. (LO)** (U.S. Patent 6,151,565).

12.1 As per Claim 31, **MO, MA, LE** and **HU** teach the method of claim 27. **MO, MA, LE** and **HU** do not expressly teach that the values for the property weights w_j are obtained using an algorithm based on an analytic hierarchy process. **LO** teaches that the values for the property weights w_j are obtained using an algorithm based on an analytic hierarchy process (Col 1, Lines 47-56), as that determines the weighting of various factors using pair-wise comparison of the factors, each factor being compared to each other factor after the factors are arranged in a hierarchical order (Col 1, Lines 49-56). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO, MA, LE** and **HU** with the method of **LO** that included the values for the property weights w_j being obtained using an algorithm based on an analytic hierarchy process, as that would determine the weighting of various factors using pair-wise comparison of the factors,, each factor being compared to each other factor after the factors are arranged in a hierarchical order.

13. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459), **Lemelson (LE)** (U.S. Patent 5,871,805) and **Huse et al. (HU)** (U.S. Patent 5,862,514), and further in view of **Lobley et al. (LO)** (U.S. Patent 6,151,565) and **Li (LI)** (U.S. Patent 4,368,509).

13.1 As per Claim 32, **MO**, **MA**, **LE**, **HU** and **LO** teach the method of claim 31. **MO**, **MA**, **LE**, **HU** and **LO** do not expressly teach that the given property data are obtained through a number *l* of experimental runs of the process using the given parameter data, each the run using a distinct set of values for the given parameter data. **LI** teaches that the given property data are obtained through a number *l* of experimental runs of the process using the given parameter data, each the run using a distinct set of values for the given parameter data (Col 3, Lines 38-43; Col 4, Lines 16-44; Col 8, Table 1), as that allows analyzing the data to determine the functional relationship between the variables and the properties (Col 3, Lines 43-46). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE**, **HU** and **LO** with the method of **LI** that included the given property data being obtained through a number *l* of experimental runs of the process using the given parameter data, each the run using a distinct set of values for the given parameter data, as that would allow analyzing the data to determine the functional relationship between the variables and the properties.

14. Claims 33, 43, 46, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459), **Lemelson (LE)** (U.S. Patent 5,871,805), **Huse et al. (HU)** (U.S. Patent 5,862,514), **Lobley et al. (LO)** (U.S. Patent 6,151,565) and **Li (LI)** (U.S. Patent 4,368,509), and further in view of **NIST (NI)** (Engineering Statistics Handbook).

14.1 As per Claim 33, **MO, MA, LE, HU, LO** and **LI** teach the method of claim 32. **MO, MA, LE, HU, LO** and **LI** do not expressly teach that the number of experimental runs of the process each uses a selected distinct set of values for the parameters X_i covering substantially all extreme values within a chosen range of values for each one of the parameters X_i . **NI** teaches that the number of experimental runs of the process each uses a selected distinct set of values for the parameters X_i covering substantially all extreme values within a chosen range of values for each one of the parameters X_i (Page 8, Para 2 and Page 9, Para 1), as that gives most of the information required (Page 8, Para 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO, MA, LE, HU, LO** and **LI** with the method of **NI** that included that the number of experimental runs of the process each using a selected distinct set of values for the parameters X_i covering substantially all extreme values within a chosen range of values for each one of the parameters X_i , as that would give most of the information required.

MO, MA, LE, HU and **LO** do not expressly teach that l is at least equal to $n + 1$ and is substantially less than a number used in the Fractional Factorial Matrix method. **NI** teaches that a fractional factorial design is one in which only an adequately chosen fraction of the combinations required for the complete factorial experiments is selected to be run (Page 11, Para 1) and a fraction such as $1/2$, $1/4$ etc. of the runs called for by full factorial is selected (Page 11, Para 3), as that would reduce the resource requirements for the runs (Page 11, Para 2). **LI** teaches that l is at least equal to $n + 1$ and is substantially less than a number used in the Fractional Factorial Matrix method (Col 4, Lines 16-44; Col 8, Table 1), as the savings in resources required is substantial (Col 5, Lines 2-3). It would have been obvious to one of ordinary skill in

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the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE**, **HU** and **LO** with the method of **LI** that included l at least equal to $n + 1$ and substantially less than a number used in the Fractional Factorial Matrix method, as the savings in resources required would be substantial.

14.2 As per Claim 43, **MO**, **MA**, **LE**, **HU**, **NI** and **LI** teach the method of claim 42. **MO**, **MA**, **LE**, **HU**, **NI** and **LI** do not expressly teach that the values for the property weights w_j are obtained using an algorithm based on an analytic hierarchy process. **LO** teaches that the values for the property weights w_j are obtained using an algorithm based on an analytic hierarchy process (Col 1, Lines 47-56), as that determines the weighting of various factors using pair-wise comparison of the factors, each factor being compared to each other factor after the factors are arranged in a hierarchical order (Col 1, Lines 49-56). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE**, **HU**, **NI** and **LI** with the method of **LO** that included the values for the property weights w_j being obtained using an algorithm based on an analytic hierarchy process, as that would determine the weighting of various factors using pair-wise comparison of the factors,, each factor being compared to each other factor after the factors are arranged in a hierarchical order.

14.3 As per Claim 46, **MO**, **MA**, **LE**, **HU**, **NI**, **LI** and **LO** teach the method of claim 43. **MO**, **MA**, **LE**, **HU**, **NI** and **LO** do not expressly teach that $l = n + 1$. **LI** teaches that $l = n + 1$ (Col 4, Lines 16-44; Col 8, Table 1), as the savings in resources required is substantial (Col 5, Lines 2-3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's

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invention to modify the method of **MO**, **MA**, **LE**, **HU**, **NI** and **LO** with the method of **LI** that included l at least equal to $n + 1$ and substantially less than a number used in the Fractional Factorial Matrix method, as the savings in resources required would be substantial.

14.4 As per Claim 50, **MO**, **MA**, **LE**, **NI**, **LI** and **HU** teach the method of claim 41. **MO** also teaches performing experimentally the process using the set of optimal parameters values to obtain corresponding experimental values for the properties Y_j (Col 2, Lines 17-23).

MO, **MA**, **LE**, **NI**, **LI** and **HU** do not expressly teach ranking the set of optimal parameters values over predetermined alternative sets of parameters values for the X_i . **LO** teaches ranking the set of optimal parameters values over predetermined alternative sets of parameters values for the X_i (Col 1, Lines 47-56), as that allows comparison of each factor to each other factor after the factors are arranged in a hierarchical order and determination of the weighting of various factors using pair-wise comparison of the factors (Col 1, Lines 49-56). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE**, **NI**, **LI** and **HU** with the method of **LO** that included ranking the set of optimal parameters values over predetermined alternative sets of parameters values for the X_i , as that would allow comparison of each factor to each other factor after the factors were arranged in a hierarchical order and determination of the weighting of various factors using pair-wise comparison of the factors.

14.5 As per Claim 51, **MO**, **MA**, **LE**, **NI**, **LI**, **HU** and **LO** teach the method of claim 50. **MO**, **MA**, **LE**, **NI**, **LI** and **HU** do not expressly teach that the ranking step is performed using an

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algorithm based on an analytic hierarchy process. **LO** teaches that the ranking step is performed using an algorithm based on an analytic hierarchy process (Col 1, Lines 47-56), as that allows comparison of each factor to each other factor after the factors are arranged in a hierarchical order and determination of the weighting of various factors using pair-wise comparison of the factors (Col 1, Lines 49-56). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE**, **NI**, **LI** and **HU** with the method of **LO** that included the ranking step being performed using an algorithm based on an analytic hierarchy process, as that would allow comparison of each factor to each other factor after the factors were arranged in a hierarchical order and determination of the weighting of various factors using pair-wise comparison of the factors.

15. Claims 40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459), **Lemelson (LE)** (U.S. Patent 5,871,805), and **Li (LI)** (U.S. Patent 4,368,509), and further in view of **NIST (NI)** (Engineering Statistics Handbook).

15.1 As per claim 40, **MO** teaches a method of producing a product using a process, the process being essentially controlled by a set of n parameters X_i characterizing a formulation for the product, the parameters X_i affecting a set of k properties Y_j characterizing the product (Col 1, Lines 8-11); the method comprising:

measuring values for the properties Y_i characterizing the product in each of the l experimental runs, whereby parameter data and associated property data are obtained from the

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selected distinct set of values for the parameters X_i and the measured values for the properties Y_j , respectively (Col 1, Lines 58-59; Col 2, Lines 17-23).

MO does not expressly teach a method of producing a product using optimized process parameter values. **LE** teaches using the a method of producing a product using optimized process parameter values (Col 1, Lines 5-7; Col 4, Line 66 to Col 5, Line 2), as that will tailor the process to the process goals (Col 4, Lines 63-64). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO** with the method of **LE** that included a method of producing a product using optimized process parameter values, as that would tailor the process to the process goals.

MO and **LE** do not expressly teach conducting a number of l of experimental runs of the process each using a selected distinct set of values for the parameters X_i covering substantially all extreme values within a chosen range of values for each one of the parameters X_i . **NI** teaches conducting a number of l of experimental runs of the process each using a selected distinct set of values for the parameters X_i covering substantially all extreme values within a chosen range of values for each one of the parameters X_i (Page 8, Para 2 and Page 9, Para 1), as that gives most of the information required (Page 8, Para 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO** and **LE** with the method of **NI** that included conducting a number of l of experimental runs of the process each using a selected distinct set of values for the parameters X_i covering substantially all extreme values within a chosen range of values for each one of the parameters X_i , as that would give most of the information required.

MO, LE and **NI** do not expressly teach that l is at least equal to $n + 1$ and is substantially less than a number used in the Fractional Factorial Matrix method. **NI** teaches that a fractional factorial design is one in which only an adequately chosen fraction of the combinations required for the complete factorial experiments is selected to be run (Page 11, Para 1) and a fraction such as $1/2$, $1/4$ etc. of the runs called for by full factorial is selected (Page 11, Para 3), as that would reduce the resource requirements for the runs (Page 11, Para 2). **LI** teaches that l is at least equal to $n + 1$ and is substantially less than a number used in the Fractional Factorial Matrix method (Col 4, Lines 16-44; Col 8, Table 1), as the savings in resources required is substantial (Col 5, Lines 2-3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO, LE** and **NI** with the method of **LI** that included l at least equal to $n + 1$ and substantially less than a number used in the Fractional Factorial Matrix method, as the savings in resources required would be substantial.

MO, LE, NI and **LI** do not expressly teach determining an importance of the properties Y_j for the characterization of the product, comparing the importance of the properties Y_j relative to one another, and assigning values to a set of k property weights w_j representing a relative importance of the properties Y_j for the characterization of the product. **MA** teaches determining an importance of the properties Y_j for the characterization of the product, comparing the importance of the properties Y_j relative to one another, and assigning values to a set of k property weights w_j representing a relative importance of the properties Y_j for the characterization of the product (Col 15, Lines 11-22), as weighting provides different importance to different properties (Col 16, Lines 26-27) and it adds robustness to handle mismatch between process and prediction mode (Col 15, Lines 52-54). It would have been obvious to one of

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ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **LE**, **NI** and **LI** with the method of **MA** that included determining an importance of the properties Y_j for the characterization of the product, comparing the importance of the properties Y_j relative to one another, and assigning values to a set of k property weights w_j representing a relative importance of the properties Y_j for the characterization of the product, as weighting would provide different importance to different properties and it would add robustness to handle mismatch between process and prediction mode.

MO, **NI**, **LI** and **MA** does not expressly teach calculating a set of optimal parameter values for the parameters X_i using the measured values for the properties Y_j and the assigned values of the set of k property weights w_j . **LE** teaches calculating a set of optimal parameter values for the parameters X_i using the measured values for the properties Y_j (Col 10, Lines 2-15), as the values so selected for the parameters will reflect the best outcome for the properties (Col 10, Lines 12-14). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **NI**, **LI** and **MA** with the method of **LE** that included calculating a set of optimal parameter values for the parameters X_i using the measured values for the properties Y_j , as the values so selected for the parameters would reflect the best outcome for the properties.

MO, **NI**, **LI** and **LE** do not expressly teach calculating a set of optimal parameter values for the parameters X_i using the assigned values of the set of k property weights w_j . **MA** teaches calculating a set of optimal parameter values for the parameters X_i using the assigned values of the set of k property weights w_j (Col 14, Lines 4-6; Col 15, Lines 11-22), as weighting provides different importance to different properties in the objective or goal function (Col 16, Lines 26-

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27) and it adds robustness to handle mismatch between process and prediction mode (Col 15, Lines 52-54). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **NI**, **LI** and **LE** with the method of **MA** that included calculating a set of optimal parameter values for the parameters X_i using the assigned values of the set of k property weights w_j , as weighting would provide different importance to different properties in the objective or goal function and it would add robustness to handle mismatch between process and prediction mode.

MO, **NI**, **LI** and **MA** do not expressly teach producing the product using the optimized process parameter values X_i calculated in the previous step. **LE** teaches producing the product using the optimized process parameter values X_i calculated in the previous step (Col 1, Lines 5-7; Col 4, Line 66 to Col 5, Line 2), as that will tailor the process to the process goals (Col 4, Lines 63-64). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **NI**, **LI** and **MA** with the method of **LE** that included producing the product using the optimized process parameter values X_i calculated in the previous step, as that would tailor the process to the process goals.

15.2 As per Claim 44, **MO**, **MA**, **LE**, **NI** and **LI** teach the method of claim 40. **MO**, **MA**, **LE** and **NI** do not expressly teach that $l = n + 1$. **LI** teaches that $l = n + 1$ (Col 4, Lines 16-44; Col 8, Table 1), as the savings in resources required is substantial (Col 5, Lines 2-3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE** and **NI** with the method of **LI** that included l at least equal to $n + 1$ and

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substantially less than a number used in the Fractional Factorial Matrix method, as the savings in resources required would be substantial.

16. Claims 41, 42, 45, 47-49 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mozzo (MO)** (U.S. Patent 5,218,526) in view of **Martin et al. (MA)** (U.S. Patent 6,487,459), **Lemelson (LE)** (U.S. Patent 5,871,805), **Huse et al. (HU)** (U.S. Patent 5,862,514), and **Li (LI)** (U.S. Patent 4,368,509), and further in view of **NIST (NI)** (Engineering Statistics Handbook).

16..1 As per Claim 41, **MO, MA, LE, NI** and **LI** teach the method of claim 40. **MO, MA, LE, NI** and **LI** do not expressly teach that the product is a pharmaceutical product, and the process is a formulation of the product. **HU** teaches that the product is a pharmaceutical product, and the process is a formulation of the product (Col 2, Lines 41-54), as that enhances the efficiency with which the drugs are discovered and developed (Col 2, Lines 43-45). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO, MA, LE, NI** and **LI** with the method of **HU** that included the product being a pharmaceutical product, and the process is a formulation of the product, as that would enhance the efficiency with which the drugs are discovered and developed.

16..2 As per Claim 42, **MO, MA, LE, NI, LI** and **HU** teach the method of claim 41. **MO** also teaches that the step of calculating comprises establishing property behavior mathematical

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relations giving an estimated property Y_{ej} for each the property Y_j in terms of the parameters X_i from given parameter data and associated property data (Col 1, Lines 42-49; Col 1, Lines 53-61).

MO teaches using the property to establish a goal function in terms of property deviations between the estimated properties Y_{ej} and corresponding specified goal values for the properties Y_j (Col 1, Line 67 to Col 2, Line 23). **MO** does not expressly teach using the property weights w_j to establish a goal function in terms of property weighted deviations between the estimated properties Y_{ej} and corresponding specified goal values for the properties Y_j . **MA** teaches using the property weights w_j to establish a goal function in terms of property weighted deviations between the estimated properties Y_{ej} and corresponding specified goal values for the properties Y_j (Col 14, Lines 4-6; Col 15, Lines 11-22), as weighting provides different importance to different properties in the objective or goal function (Col 16, Lines 26-27) and it adds robustness to handle mismatch between process and prediction mode (Col 15, Lines 52-54). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO** with the method of **MA** that included using the property weights w_j to establish a goal function in terms of property weighted deviations between the estimated properties Y_{ej} and corresponding specified goal values for the properties Y_j , as weighting would provide different importance to different properties in the objective or goal function and it would add robustness to handle mismatch between process and prediction mode.

MO teaches minimizing the goal function (Col 2, Lines 33-34). **MO** does not expressly teach minimizing the goal function to generate a set of n optimal parameter values for the parameters X_i . **LE** teaches minimizing the goal function to generate a set of n optimal parameter

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values for the parameters X_i (Col 10, Lines 2-15), as the values so selected for the parameters will reflect the best outcome for the properties (Col 10, Lines 12-14). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO** with the method of **LE** that included minimizing the goal function to generate a set of n optimal parameter values for the parameters X_i , as the values so selected for the parameters would reflect the best outcome for the properties.

16.3 As per Claim 45, **MO**, **MA**, **LE**, **NI**, **LI** and **HU** teach the method of claim 42. **MO**, **MA**, **LE**, **NI** and **HU** do not expressly teach that $l = n + 1$. **LI** teaches that $l = n + 1$ (Col 4, Lines 16-44; Col 8, Table 1), as the savings in resources required is substantial (Col 5, Lines 2-3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **LE**, **NI** and **HU** with the method of **LI** that included l at least equal to $n + 1$ and substantially less than a number used in the Fractional Factorial Matrix method, as the savings in resources required would be substantial.

16.4 As per Claim 47, **MO**, **MA**, **LE**, **NI**, **LI** and **HU** teach the method of claim 41. **MO**, **LE**, **NI**, **LI** and **HU** do not expressly teach that the goal function is expressed as $G(X_1, \dots, X_n) = \sum_{i=1}^k w_j^2 (Y_{ej} - O_j)^2$ wherein O_j are the specified goal values for the properties Y_j . **MA** teaches that the goal function is expressed as $G(X_1, \dots, X_n) = \sum_{i=1}^k w_j^2 (Y_{ej} - O_j)^2$ wherein O_j are the specified goal values for the properties Y_j (Col 15, Lines 11-22), as weighting provides different importance to different properties (Col 16, Lines 26-27) and it adds robustness to handle mismatch between process and prediction mode (Col 15, Lines 52-54) and minimizing the square

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of errors gives importance to a few large errors over many small errors. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **LE**, **NI**, **LI** and **HU** with the method of **MA** that included assigning values to a set of k property weights w_j representing relative importance of the properties Y_j for the characterization of the product, as weighting would provide different importance to different properties and it would add robustness to handle mismatch between process and prediction mode and minimizing the square of errors would give importance to a few large errors over many small errors.

16.5 As per Claim 48, **MO**, **MA**, **LE**, **NI**, **LI** and **HU** teach the method of claim 47. **MO**, **MA**, **NI**, **LI** and **HU** do not expressly that the minimizing step is performed through successive iterations. **LE** teaches that the minimizing step is performed through successive iterations (Col 10, Lines 2-15), as the values so selected for the parameters will reflect the best outcome for the properties (Col 10, Lines 12-14). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **NI**, **LI** and **HU** with the method of **LE** that included the minimizing step being performed through successive iterations, as the values so selected for the parameters would reflect the best outcome for the properties.

16.6 As per Claim 49, **MO**, **MA**, **LE**, **NI**, **LI** and **HU** teach the method of claim 48. **MO** also teaches that the goal function is minimized according to one or more specified ranges (a_i, b_i) wherein $a_i < X_i < b_i$ for one or more of the optimal parameter values (Col 2, Lines 17-23).

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16.7 As per Claim 52, **MO**, **MA**, **LE**, **NI**, **LI** and **HU** teach the method of claim 41. **MO** also teaches incorporating the set of optimal parameters values and the corresponding experimental values for the properties Y_j respectively into the given parameter and associated property data (Col 1, Lines 58-59).

MO, **MA**, **NI**, **LI** and **HU** do not expressly teach repeating the steps ii) to iv) to generate a new set of optimal parameters values for the parameters X_i . **LE** teaches repeating the steps ii) to iv) to generate a new set of optimal parameters values for the parameters X_i (Col 10, Lines 2-15), as the values so selected for the parameters will reflect the best outcome for the properties (Col 10, Lines 12-14). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **MO**, **MA**, **NI**, **LI** and **HU** with the method of **LE** that included repeating the steps ii) to iv) to generate a new set of optimal parameters values for the parameters X_i , as the values so selected for the parameters would reflect the best outcome for the properties.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure.

The following patents are cited to further show the state of the art with respect to experiments design for producing a product having n parameters and k properties using optimal formulation of the product..

1. Martin et al., "Method and apparatus for modeling dynamic ... and optimization", U.S. Patent 6,487,459, November 2002.
2. Lemelson, "Computer controlled vapor deposition processes", U.S. Patent 5,871,805, February 1999.
3. Huse et al., "Method and means for synthesis based simulation of chemicals having biological functions", U.S. Patent 5,862,514, January 1999.
4. Lobley et al., "Decision support system, method and article of manufacture", U.S. Patent 6,151,565, November 2000.
4. Li, "Self-optimizing machine and method", U.S. Patent 4,368,509, January 1983.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 703-305-0043. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

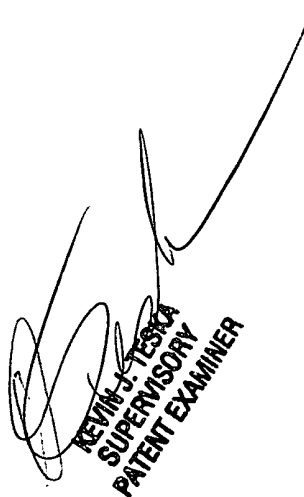
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska, can be reached on (703) 305-9704. The fax phone number for the organization where this application or proceeding is assigned is 703-746-7329.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9600.

K. Thangavelu
Art Unit 2123
March 5, 2003



KEVIN J. TESKA
SUPERVISORY
PATENT EXAMINER